DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

3041. Misbranding of Dexedrine Sulfate Tablets and Benzedrine Sulfate Tablets. U. S. v. Armand G. Crawford (Crawford Pharmacies), Carl Hendricks, and Garland A. Butt. Pleas of nolo contendere. Defendants placed on probation for 1 year. (F. D. C. No. 26734. Sample Nos. 45561-K, 45562-K, 46183-K, 46187-K, 46233-K, 46234-K.)

INFORMATION FILED: September 26, 1949, Western District of Arkansas, against Armand G. Crawford, trading as Crawford Pharmacies, and Carl Hendricks and Garland A. Butt, pharmacists.

INTERSTATE SHIPMENT: Prior to the date of the sales of the Dexedrine Sulfate Tablets and the Benzedrine Sulfate Tablets by the defendant as hereinafter described, the tablets were shipped in interstate commerce from the State of Pennsylvania into the State of Arkansas.

LABEL, WHEN SHIPPED: (On number of bottles) "Dexedrine Sulfate Tablets

* * Caution: To be dispensed only by or on the prescription of a
physician" or "Benzedrine Sulfate Tablets * * * Caution: To be dispensed only by or on the prescription of a physician."

ALLEGED VIOLATION: On or about December 30, 1948, and February 4, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused a number of tablets of the drugs to be removed from the bottles in which they had been shipped, to be repacked into boxes, small bottles, and envelopes, and to be sold to various persons without a prescription, which acts of the defendants resulted in the repackaged tablets being misbranded. Portions of the repackaged tablets were labeled in part "A. G. Crawford Pharmacies * * * Dexedrine Sulfate 5 mg." "Dexedrine Contents 5 mg. Packed by A. G. Crawford Pharmacies," "A. G. Crawford Pharmacies," or "Benzedrine 50 mg."

The containers involved in one sale of the *Dexedrine Sulfate Tablets* and in one sale of the *Benzedrine Sulfate Tablets* were unlabeled.

NATURE OF CHARGE: Adulteration, Section 501 (c), (1 lot of Benzedrine Sulfate Tablets) the strength of the tablets differed from that which they purported and were represented to possess since each tablet was represented to contain 50 milligrams of Benzedrine, whereas each tablet contained less than 50 milligrams of Benzedrine.

Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents; Section 502 (f) (1), the articles failed to bear labeling containing adequate directions for use; Section 502 (b) (1), (2 lots of Benzedrine Sulfate Tablets and 1 lot of Dexedrine Sulfate Tablets) the articles failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (e) (1), (1 lot of Dexedrine Sulfate Tablets and 2 lots of Benzedrine Sulfate Tablets) the repackaged tablets failed to bear the common or usual name of the drugs; and, Section 502 (a), (1 lot of Benzedrine Sulfate Tablets) the label statement "Benzedrine 50 mg." was false and misleading since the tablets contained less than 50 milligrams of Benzedrine.

Disposition: October 3, 1949. Pleas of nolo contendere having been entered, the defendants were placed on probation for 1 year.

- 3042. Misbranding of thyroid tablets, phenobarbital tablets, sodium pentobarbital capsules, and Benzedrine Sulfate Tablets. U. S. v. Warren U. Rice (Rice Drug Store). Plea of guilty. Defendant fined \$750 and placed on probation for 1 year. (F. D. C. No. 28114. Sample Nos. 60778-K, 60802-K, 60806-K, 60808-K, 60817-K, 60818-K.)
- INFORMATION FILED: January 17, 1950, Eastern District of Illinois, against Warren U. Rice, trading as the Rice Drug Store, Centralia, Ill.
- INTERSTATE SHIPMENT: Between November 18, 1947, and June 6, 1949, from the State of Missouri into the State of Illinois, of quantities of thyroid tablets, phenobarbital tablets, sodium pentobarbital capsules, and Benzedrine Sulfate Tablets.
- ALLEGED VIOLATION: On or about June 2, 6, and 13, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the drugs to be removed from the bottles in which they had been shipped, to be repacked into envelopes, and to be sold without a prescription; and the defendant caused also a quantity of phenobarbital tablets that were contained in the original bottle which was shipped in interstate commerce, to be sold without a prescription, which acts of the defendant resulted in the drugs being misbranded.
- NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (b) (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of the contents.

Further misbranding, Section 502 (d), the repackaged sodium pentobarbital capsules, the repackaged phenobarbital tablets, and the phenobarbital tablets sold in the original bottle, contained derivatives of barbituric acid, which derivatives had been found to be, and by regulations designated by the Administrator of the Federal Surcity Agency as, habit forming; and the labels failed to bear the name, and quantity or proportion of the derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged Benzedrine Sulfate Tablets were not designated solely by a name recognized in an official compendium, and their labels failed to bear the common or usual name of the drug, namely, Benzedrine Sulfate; and, Section 502 (f) (1), the repackaged drugs and the phenobarbital tablets sold in the original bottle, bore no labeling containing directions for use.

- DISPOSITION: January 31, 1950. A plea of guilty having been entered, the court imposed a fine of \$750 and placed the defendant on probation for 1 year.
- 3043. Misbranding of nembutal sodium capsules, seconal sodium capsules, and Benzedrine Sulfate Tablets. U. S. v. Charles H. Stagner (East Erwin Drug Co.). Plea of guilty. Fine, \$50. (F. D. C. No. 26749. Sample Nos. 23850-K, 23856-K, 23864-K, 23873-K, 23876-K, 53206-K, 53207-K.)
- LIBEL FILED: November 10, 1949, Eastern District of Texas, against Charles H. Stagner, trading and doing business as the East Erwin Drug Co., Tyler, Tex.
- INTERSTATE SHIPMENT: The information alleged that the seconal sodium capsules, the Benzedrine Sulfate Tablets, and a portion of the nembutal sodium capsules had been shipped in interstate commerce between the approximate dates of April 12, 1948, and January 17, 1949, from North Chicago, Ill., Indianapolis, Ind., and Philadelphia, Pa., and that the remainder of the nembutal sodium capsules had been manufactured at North Chicago, Ill., and shipped in interstate commerce into the State of Texas.